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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,221	07/18/2003	Martin O'Sullivan	50571/AW/W112	4670
23363	7590	06/29/2005	EXAMINER	
CHRISTIE, PARKER & HALE, LLP			ROANE, AARON F	
PO BOX 7068			ART UNIT	
PASADENA, CA 91109-7068			PAPER NUMBER	
			3739	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,221

Applicant(s)

O'SULLIVAN ET AL.

Examiner

Aaron Roane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 33 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/8/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-31 in the reply filed on 4/7/2005 is acknowledged.
2. Applicant's election with traverse of Species I, single electrode catheter in the reply filed on 4/7/2005 is acknowledged.

However, as stated in the previous office action (mailed 2/10/2005):

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant has clearly admitted on the record (see response filed 4/7/2005 page 2, lines 1-8) that Species I and II are obvious variants of each other and not patentably distinct.

Therefore, if the examiner finds one of the inventions unpatentable over the prior art, the

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evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Applicant's election without traverse of Subspecies B, the wrapped coil electrode in the reply filed on 4/7/2005 is acknowledged.
4. Applicant's election with traverse of Sub-subspecies I, the nylon porous sleeve in the reply filed on 4/7/2005 is acknowledged.

However, as stated in the previous office action (mailed 2/10/2005):

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant has clearly admitted on the record (see response filed 4/7/2005 beginning page 2, 5th line from the bottom of the page through page 3, line 5) that Sub-subspecies I-IV are all obvious variants of each other and not patentably distinct. Therefore, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant's election with traverse of Sub-sub-species alpha in the reply filed on 4/7/2005 is acknowledged.

It should be noted here, the requirement for the election of Sub-sub-species between alpha and beta is as pointed out by Applicant (see page 3 last paragraph) is improper as figures 6 and 7 are simply different views of the same object from different observation points.

Therefore, the examiner will examine claims 1-32*.

* It should be noted that there is an error in the numbering of the claims. There are two (2) claims numbered 23, the first claim 23 is at the bottom of page 18 while the second claim 23 (renumbered 24) is at the top of page 19. See the Objections to the claims below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 6 of claim 1 and line 8 of claim 17, the claims recite "one or more electrodes electrically connected to a suitable energy source". However, Applicant's claims are directed to a catheter and not a system comprising a catheter and an electrical energy source. The problem with the above recitation is specifically the phrase "electrically connected to a suitable energy source". The examiner suggests amending such that "one or more electrodes electrically connected to a suitable energy source" becomes --one or more electrodes capable of being electrically connected to a suitable energy source— or --one or more electrodes electrically connectable to a suitable energy source— and will interpret the above recitation as such.

Additionally,

- Claim 5 recites the limitation "the porous electrode" in line 1. There is insufficient antecedent basis for this limitation in the claim.
 - The examiner will interpret this as –the porous electrode arrangement--.
- Claims 6 and 20 both recite the limitation "the generally straight porous electrode" in line 1. There is insufficient antecedent basis for this limitation in the claim.

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- The examiner will interpret this as –the porous electrode arrangement is generally straight and--.
- Claim 8 recites the limitation "the porous electrode" in line 1. There is insufficient antecedent basis for this limitation in the claim.
 - The examiner will interpret this as –the porous electrode arrangement--.
- Claims 12, 13, 25 and 26 all recite the limitation "the porous electrode" in line 1. There is insufficient antecedent basis for this limitation in the claim.
 - The examiner will interpret this as –the porous electrode arrangement--.
- Claims 14 and 27 both recite the limitation "the porous electrode" in line 2. There is insufficient antecedent basis for this limitation in the claim.
 - The examiner will interpret this as –the porous electrode arrangement--.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they

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must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 23-33 have been renumbered 23-34.

Here is a chart illustrating how the examiner has renumbered the claims.

<u>OLD CLAIMS</u>	<u>depended on</u>	<u>NEW CLAIMS</u>	<u>now depends on</u>
23 (page 18)	17	23	17
23 (page 19)	17	24	17
24	17	25	17
25	17	26	17
26	17	27	17
27	17	28	17
28	27	29	28
29	27	30	28
30	29	31	30
31	17	32	17
32 (withdrawn)	Independent	33	Independent
33 (withdrawn)	Independent	34	Independent

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Whayne et al. (USPN 6,203,525 B1).

Regarding claims 1, 2, 5 and 17, Whayne et al. disclose a catheter for ablating tissue, the catheter comprising: an elongated generally-tubular catheter body (12 in figure 1 and its analogous counterparts in other embodiments) having proximal and distal ends; and an electrode assembly (360 in figure 36-38) at the distal end of the catheter body, the electrode assembly including a generally-straight porous electrode arrangement that is generally transverse to the catheter body, the porous electrode arrangement comprising: one or more electrodes (the left and center electrodes 372 in figures 37 and 38) electrically connected to a suitable energy source (not shown see col. 5, lines 50-67, also see 380 in col. 22, lines 1-3); a porous sleeve (364) mounted in surrounding relation to the one or more electrodes; and one or more irrigation openings (374) fluidly connecting the open space to a lumen (lumen of 370) extending through the catheter through which fluid can pass; wherein, in use, fluid passes through the lumen in the catheter, through the

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one or more irrigation openings, into the open space and through the porous sleeve, see col. 5, 6 and 21-23 and figures 1 and 36-38. Regarding the electrode assembly further comprising a non-conductive tubing mounted on the distal end of the catheter over which the one or more electrodes are mounted, and wherein the non-conductive tubing includes at least one lumen fluidly connected to the lumen in the catheter body and to the one or more irrigation openings, Wayne et al. are silent as to the tubing (370) over which the one or more electrodes are mounted is non-conductive. However, Wayne et al. certainly imply that the tubing (370) is electrically non-conductive since it discusses the use of the electrodes (372) in a bipolar mode, see col. 21. The tubing (370) would have to be non-conductive the electrodes (372) are used in bipolar mode, otherwise the tubing (372) would provide an electrical "short" between the electrodes.

Regarding claims 3 and 18, Wayne et al. further disclose the one or more electrodes comprises a single coiled electrode (22) wrapped around a portion of the non-conductive tubing, see col. 5-8 and 23.

Regarding claims 4 and 19, Wayne et al. further disclose the porous sleeve has proximal and distal ends that are bonded to the non-conductive tubing, see figure 38.

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Regarding claims 6 and 20, Wayne et al. further disclose the generally straight porous electrode forms an angle with the axis of the catheter body ranging from about 75° to about 110°, see col. 5-23 and figures 1-39.

Regarding claims 7 and 21, Wayne et al. further disclose the non-conductive tubing is capable of forming a curve that first bends away from and then back toward and past the axis of the catheter body, and has a straight distal end over which the porous electrode is mounted, see col. 5-23 and figures 1-39.

Regarding claim 8, Wayne et al. disclose the claimed invention, see figures 1-39.

Regarding claims 9, 10, 22 and 23, Wayne et al. further the porous sleeve comprises a polytetrafluoroethylene (PTFE) that is expandable to no more than 10% at a distilled water flow rate of 30 to 40 cc/min, see col. 21 and 22.

Regarding claims 11 and 24, Wayne et al. further disclose the porous sleeve comprises a material selected from the group consisting of porous nylon, sintered ceramics, woven meshes and cellular foam, see col. 22, line 39-57.

Regarding claims 12, 13, 25 and 26, Wayne et al. disclose the claimed invention, see col. 5-25 and particularly col. 23.

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Regarding claims 14 and 27, Wayne et al. further disclose the electrode assembly further comprises one or more ring electrodes (the right electrode 372 in figures 37 and 38) mounted proximal and/or distal to the porous electrode (the left and center electrodes 372 in figures 37 and 38).

Regarding claims 15, 16, 28 and 29, Wayne et al. further disclose the electrode assembly further comprises one or more temperature sensors (see for example 292 figure 29), wherein the one or more temperature sensors are mounted under the porous sleeve, see col. 23-25 and figure 29.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wayne et al. (USPN 6,203,525 B1) in view of Fung et al. (USPN 6,120,476).

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Regarding claims 30 and 31, Whayne et al. disclose the claimed invention except that a pre-shaped support wire made of nitinol extends through a second lumen of the non-conductive tubing. Whayne et al. clearly discloses a first lumen (lumen of 370) used for irrigation, see col. 5, 6 and 21-23 and figures 1 and 36-38. Whayne et al. also disclose the use of a nitinol pre-shaped support wire (26) located in a lumen of a non-conductive tubing (28 and/or 28'). However, Whayne et al. do not disclose simultaneously disposing a nitinol pre-shaped support wire in one lumen of the non-conductive tubing and the having an irrigating pathway/passage in other separate lumen. Fung et al. disclose an irrigated tip-catheter that has at least two lumens and teach the provision of the non-conductive tubing (19) upon which electrodes (38) are placed with three lumens 30, 32 and 34, see col. 4-6 and figure 3. Additionally, Fung et al. teach the simultaneous provision of a pre-shaped nitinol wire (42) placed in one lumen (32) in order to provide steerability/deflection of the device and the use of another lumen (34) as an irrigation lumen in order to provide infusion, see col. 4-6 and figure 3. Therefore, at the time of the invention it would have been obvious to modify the invention of Whayne et al., as taught by Fung et al., to simultaneously provide the pre-shaped nitinol wire placed in one lumen in order to provide steerability/deflection of the device and the use of another lumen as an irrigation lumen in order to provide infusion.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whayne et al. (USPN 6,203,525 B1) in view of Swanson et al. (USPN 5,961,513).

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Regarding claim 32, Whayne et al. disclose the claimed invention except for reciting the one or more irrigation openings are located only on the side of the porous electrode that is to be in contact with tissue to be ablated. It is well known in the art to place or provide holes/pores of a porous material in a particular pattern and/or on a side of the otherwise porous material in order to achieve a particular ablation pattern. Swanson et al. disclose a tissue heating and/or ablating device and teach providing the expandable porous element (22) with holes/pores located on one side in order to achieve a particular ablation pattern and/or serve as a sensing surface, see col. 5-21 and figures 1-14. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Whayne et al., as is well known in the art and taught by Swanson et al., to provide the expandable porous element with holes/pores located on one side in order to achieve a particular ablation pattern and/or serve as a sensing surface.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



A.R. A.R.

Lee Cohen
Primary Examiner

June 23, 2005